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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,293	12/18/2001	Masanori Ayabe	350292001100	1682

25227 7590 04/24/2006

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EXAMINER
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HAAS, WENDY C

ART UNIT	PAPER NUMBER
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1661

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/018,293

**Applicant(s)**

AYABE ET AL.

**Examiner**

Wendy C. Haas

**Art Unit**

1661

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Claim Objections*

In light of Applicant's amendments made 16 November 2005, Claim1 is no longer objected to.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *Allium*, does not reasonably provide enablement for all plant species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

***The breadth of the claim and the nature of the invention.*** Claims 1 and 3 are directed to making virus-free plants from any virus infected plant using the “foliage leaf base”. The foliage leaf base, as set forth in the Specification, is the lower portion of the foliage leaf or stem disc in the bulb of the plant.

***The quantity of experimentation necessary.*** The quantity of experimentation necessary would vary to a high degree with the target plant species for virus eradication. The present claim is directed towards a portion of leaves that attach to the stem disc of a bulb as an explant.

Applicant has amended that claims to now include only plants that produce bulbs and “foliage leaf bases”. However, not all bulbous plants will necessarily produce callus suitable for regeneration and/or virus eradication. *See, e.g.,* Maarten, which notes that tissue culture of tulip bulb scales is cumbersome and the bulbs are only capable of regeneration at certain times.

***The predictability or unpredictability of the art.*** The plant tissue culture art is unpredictable across genera.

***The state of the prior art and the relative skill of those in the art.*** The prior art discloses methods of virus eradication and tissue culture and regeneration for plants in the Allium family. The skill of those in the art is high.

***The amount of direction or guidance presented and the presence or absence of working examples of the invention.*** Applicant provides guidance and working examples for *Allium sativa*. Though applicant mentions that the claimed method would work with lilies, narcissuses and tulips, applicant provides no working examples, and as shown above, the prior art indicates that at least one of these plants, tulip, would not be expected to work. Applicant provides no guidance for other plant species or genera other than *Allium*.

In view of the breadth of the claims, the lack of guidance in the specification for species other than *Allium sp.*, the unpredictability of plant tissue culture transformation and regeneration, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, and 3-5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ayabe et al. in view of Verbeek et al. and Fletcher et al.

Ayabe et al. teach a tissue culture method for *Allium sativum* that includes preparing a stem disc explant, which is described as the lower 1mm of the basal parts of the immature foliage leaves, and culturing it on hormone-free LS medium to produce dome-shaped structures, then bud differentiation directly from each dome and development into shoots and bulblets.

Ayabe et al. further teach that this method can be used to create virus-free plants. Finally, Ayabe et al. teach that the basal part of the foliage leaf also appeared to be an excellent explant for producing in vitro shoots in a preliminary experiment.

Ayabe et al. do not teach isolating the dome-shaped structures from the foliage leaf base or the use of virus-infected starting material for propagation.

Verbeek et al. teach that methods to eradicate viruses from infected garlic tissues through tissue culture are known in the art.

Fletcher et al. teach isolation of callus (the dome-shaped structures of the instant application are commonly called callus in the art) in tissue culture of shallot (a closely related species).

Ayabe et al. note that in vitro shoots progressively developed from the stem disc explant, beginning as "domy tissue" at one week of culture and progressing without interference to in vitro shoots at three weeks of culture. Ayabe et al. also note that electron microscopy revealed that development of the in vitro shoots was restricted to regions surrounded by the basements of foliage leaves."

The examiner notes that the "foliage leaf base" illustrated in Fig. 1 of the instant application occupies the same structural space as the stem disc illustrated in Fig. 1 of Ayabe et al. A person of ordinary skill in the art would be motivated to use Ayabe et al's method of stem-disc culture with a virus-infected basal leaf explant to generate virus-free plants because Ayabe et al. noted the leaf base is an effective explant and garlic bulbs contain more basal leaf material so more plants could thus be produced.

Further, Ayabe et al. state (page 779) that their method is of practical use for the micropropagation of garlic plants, in particular as virus-free seed plants produced by shoot-tip culture." Ayabe et al. note that one major advantage to the method is its applicability to large scale cultivation.

As such, the method was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Claims 1 and 3-5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent Number 06197650 A in view of Ayabe et al. as modified by Verbeek et al. and Fletcher et al.

The Japanese Patent teaches a method of culturing *Allium sativum* plants from a leaf base explant in a hormone-free medium. The teachings of Ayabe et al., Verbeek et al. and Fletcher et al. are set forth above.

The Japanese Patent abstract does not teach formation of a “domy tissue”, or generation of virus-free plants. A person of ordinary skill in the art would be motivated to use the method of Japanese Patent Number 06197650 A to culture virus-free plants from callus (domy tissue) because Ayabe et al. noted the leaf base is an effective explant, creates domy tissue, and that tissue culture is an excellent method for virus eradication in garlic.

#### ***Comments***

(1) On page 4 of the remarks, applicant argues that the references do not suggest obtaining the explant material from a virus-infected plant; both Verbeek and Fletcher suggest this in their abstracts, and page 779 of Ayabe mentions the desirability of virus eradication using the method disclosed.

(2) Also on page 4 of the remarks, applicant argues that in the second 103 rejection, incorporating the ‘650 Japanese patent, the examiner fails to allege where each element of the claim is incorporated; see the abstract of each reference.

#### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Future Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Wendy C. Haas whose telephone number is (571) 272-0976. The examiner can normally be reached on Monday through Friday from 9:00 to 5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

W. C. Haas, J.D.

  
WENDY HAAS  
PATENT EXAMINER